

**Pediatric Advisory Committee Meeting**  
**Thursday-Friday, September 22-23, 2011**  
**Hilton Gaithersburg Hotel,**  
**620 Perry Parkway,**  
**Gaithersburg, Maryland, 20877**

**Thursday, September 22, 2011**

2:00 p.m.	<b>Welcome and Introductory Remarks to the Committee Members</b>	Geoffrey Rosenthal, MD, PhD Chair of Pediatric Advisory Committee Director of Pediatric & Congenital Heart Center Executive Director, Critical Care Services University of Maryland Medical Center Hospital for Children  Walter Ellenberg, PhD Designated Federal Official, Pediatric Advisory Committee Office of Pediatric Therapeutics, Office of Special Medical Programs, OC, FDA
2:15 p.m.	<b>Background Information on the Atypical Antipsychotics and the PAC Committee's Questions to the FDA</b>	Judith Cope, MD, MPH, Medical Officer, Office of Pediatric Therapeutics OC, FDA
2:20 p.m.	<b>Background of FDA Involvement in AHRQ Comparative Safety of Antipsychotics in Children and Adolescents</b>	Cynthia Kornegay, PhD, Epidemiologist Division of Epidemiology II Office of Surveillance & Evaluation, Office of Pharmacovigilance & Epidemiology, CDER
2:30 p.m.	<b>A Joint Study funded by AHRQ and FDA on Antipsychotic Use and Metabolic Effects in Children</b>  <i>Questions</i>	Tobias Gerhard, Ph.D. Assistant Professor, Ernest Mario School of Pharmacy Associate Director, Center for Education and Research on Mental Health Therapeutics Institute for Health, Health Care Policy, and Aging Research Rutgers, The State University of New Jersey
<b><u>Sessions on Pediatric focused Safety Reviews</u></b>		
3:30 p.m.	<b>Abilify (aripiprazole)</b>  <i>Questions and Recommendations</i>	Amy Taylor, MD, Medical Officer Pediatric & Maternal Health Staff, Office of New Drugs, CDER, FDA
4:05 p.m.	<b>Break</b>	
4:15 p.m.	<b>Pre-licensure Safety Data: AFLURIA (influenza virus vaccine)</b>  <i>Questions</i>	Cynthia Nolletti, MD, Medical Officer Division of Vaccines and Related Product Applications Office of Vaccines Research & Review CBER, FDA

**Pediatric Advisory Committee Meeting**  
**Thursday-Friday, September 22-23, 2011**  
**Hilton Gaithersburg Hotel,**  
**620 Perry Parkway,**  
**Gaithersburg, Maryland, 20877**

**Thursday, September 22, 2011**

4:45 p.m.	<b>AFLURIA (influenza virus vaccine)</b> Standard Review of Adverse Events  <i>Questions and Recommendations</i>	Michael Nguyen MD, Medical Officer Division of Epidemiology, Office of Biostatistics & Epidemiology (OBE), CBER, FDA
5:15 p.m.	<b>Pre-licensure Safety Data: FLUARIX (influenza virus vaccine)</b>  <i>Questions</i>	Melisse Baylor, MD, Medical Officer Division of Vaccines and Related Product Applications Office of Vaccines Research & Review CBER, FDA
5:45 p.m.	<b>FLUARIX (influenza virus vaccine)</b> Standard Review of Adverse Events  <i>Questions and Recommendations</i>	Patricia Rohan, MD, Medical Officer Division of Epidemiology, Office of Biostatistics & Epidemiology (OBE), CBER, FDA
6:30 p.m.	<b>Adjournment</b>	Geoffrey Rosenthal, MD, PhD Chair of Pediatric Advisory Committee Director of Pediatric & Congenital Heart Center Executive Director, Critical Care Services University of Maryland Medical Center Hospital for Children